REMARKS

Claims 1-27 are currently pending. No claim has been amended herein and no new matter has been presented.

35 U.S.C. § 102 Rejections Overcome

Claims 1, 2, 4, 5 and 8-25 remain rejected under 35 U.S.C. §102(b) as allegedly being anticipated by US 5,487,901 and 5,650,169 ("Conte"). Applicants disagree.

In order to anticipate a claim, a reference must teach each and every element of the claim. (*See*, MPEP §2131). Specifically, the Examiner states that Conte discloses a pharmaceutical tablet composed of an upper layer containing an active ingredient, formulated for immediate release, an intermediate layer that does not contain any active agents and it formulated with polymers as a semipermeable membranes, and a lower layer of the same formulation as the upper layer containing identical or different active agents and being *almost* completely coated with an impermeable with an insoluble polymeric coating (*emphasis added*). (*See*, Office Action at page 2). Moreover, the upper layer and corresponding gap in the coating is designed such that the upper layer is formulated for its immediate release. (*See*, Conte at column 2, line 33-34). The Examiner asserts that the method by which the tablet of claims 1, 2, 4, 5 and 8-25 is made is different from the method described in Conte but that the process by which the claimed product is made will only hold patentable weight if the process imparts function or structural limitations to the product that would distinguish it from the product of Conte, and that the process limitation of using a laser to incise the impermeable polymeric membrane in the product claims does not impart patentable weight. (*See*, Office Action at page 3).

Applicants submit that the process by which the therapeutic tablet system described in claims 1, 2, 4, 5 and 8-25 is made imparts function and structural limitations to this product that distinguish it from the product of Conte. Applicants submit that the process of making the therapeutic tablet system of claims 1, 2, 4, 5 and 8-25 causes structural differences between this system and the tablets taught in Conte giving the therapeutic tablet system of claims 1, 3 and 6-27 greater stability and a more advantageous release profile for constant steady release of the drug. These differences are described in greater detail below.

Applicants submit that the process of making the therapeutic tablet system of claims 1, 2, 4, 5 and 8-25 gives the system of claims 1, 2, 4, 5 and 8-25 greater stability than the tablets

taught in Conte. The incision(s) delimited film coating of the tablet of claims 1, 2, 4, 5 and 8-25 remains intact before contact with aqueous fluids. Thus, the laser generated incisions of the therapeutic tablet system of claims 1, 2, 4, 5 and 8-25 increase the stability of the tablet by protecting the ingredients contained in the tablet from humidity and oxidation prior to administration. (*See*, Specification at page 6, lines 24-27 and Declaration under 37 C.F.R. § 1.132 of Ubaldo Conte). Whereas the tablet in Conte does not provide any such protection of the active ingredients as the raised tops of the tablets are removed with an abrading system which scrapes out the raised tops leaving the active ingredient exposed. (*See*, Conte at Column 6, lines 1-4). Applicants submit that the tablet of the claimed invention is different that the tablet in Conte, as Conte does not provide a method to stabilize the active ingredient exposed by the abrading process.

Further, Applicants submit that the process of making the therapeutic tablet system of claims 1, 2, 4, 5 and 8-25 gives the system a more advantageous release profile for constant steady release of drug than the tablets taught in Conte. The graphs in Exhibit A, submitted herewith, illustrate that the tablets in Conte, on average, initially release over 30% of the active ingredient and after the initial release, the release profile tends to flatten out until a subsequent release occurs. In contrast, the claimed tablet has a substantially linear drug release rate, in general, the initial amount of the drug released is below 20%. (*See*, Exhibit B, submitted herewith). The incision(s) on the claimed tablet, comprises an impermeable that coating fully covers the active ingredients, which clearly alters the release profile, with a pre-determinable and programmable release rate compared to the release profiles of Conte.

Applicants submit that the process for making the therapeutic tablet system described in claims 1, 2, 4, 5 and 8-25 imparts function or structural limitations to the product that distinguish it from the product of Conte. Thus, Conte cannot anticipate claims 1, 2, 4, 5 and 8-25. Reconsideration and withdrawal is requested.

Additionally, claims 1, 3 and 6-27 remain rejected under 35 U.S.C. §102(e) as allegedly being anticipated by US 6,599,284 ("Faour"). Applicants disagree. As stated above, in order to anticipate a claim, a reference must teach each and every element of the claim. (*See*, MPEP §2131). The Examiner indicates that Faour discloses a controlled release osmotic device comprising of an outer later or external coating containing an active ingredients and a dosage which is comprises a passageway formed by laser incisions. Further, the Examiner indicated on page 5 of the previous Office Action mailed on April 6, 2006, that Faour teaches an insoluble

coating for the external layer. However, Applicants submit that Faour does not teach a film of polymeric material insoluble in aqueous fluids to form a film coating, said film coating being impermeable to aqueous fluids and containing one or more laser-generated incisions delimiting an area of geometric shape and predetermined dimensions as a function of desired release times of the one or more active ingredients as specified by claims 1, 3 and 6-27. Faour teaches that a "preformed passageway (5) in the semipermeable wall is generated...by a laser." (*See*, Faour at column 13, lines 48-50. Emphasis added). It does not teach an insoluble film containing one or more laser incisions.

Applicants submit that Faour does not teach each and every limitation of claims 1, 3 and 6-27 and thus cannot anticipate them. Reconsideration and withdrawal is requested.

Conclusion

Applicants submit that this paper is fully responsive and that the application is in condition for allowance. Should any questions arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted, Reg. No. 58,032

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Date: March 10, 2008